SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)

QAIP 5-1

PREPARING AND APPROVING QUALITY ASSURANCE IMPLEMENTING PROCEDURES

Revision 11

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REVISION HISTORY

Revision	Summary
01	Total rewrite per Dept. 6310 Procedures PMT, including auxiliary verbs, emphasized playscript format, introduced DAIs, formalized forms control, formalized identification of requirements, etc. Incorporated ICNs.
02	Updated organizational titles. Updated references. Streamlined procedures. Incorporated changes to ICNs and generally rewrote to bring the procedure up to date.
03	Added QARD Matrix Requirement Controls. Revised references. General update. Done as a result of new QARD requirements.
04	Incorporated ICN 01. Clarified review and approval responsibilities. Clarified wording for providing change rationale. Addressed QARD requirements that had not been completely addressed prior.
05	Total rewrite. Incorporated ICNs 01 and 02. Adapted to comply with QARD Revision 5. Eliminated ICNs. Changed “Rationale for Revision” to “Revision History”. Changed YMP to CRWM. Incorporated procedure categories. Defined Procedure Coordinator. Redefined use of PAR. Redefined QARD matrix. Required personnel to formally process changes resulting from a stopped work condition. Removed WIPP references (e.g. QAPD). Changed Records Center to Local Records Receiving Organization.
06	Minor changes. Changed “Request to Provide Training” form to “Request to Provide Training on Controlled Documents” form; changed effective date on the training form to the target completion date; allowed the QA Manager to initiate a new procedure or revision. Includes corrections per YM-96-D081 and YM-96-D086.
07	General rewrite to clarify process in response to DR YM-96-D004 and to incorporate OQA transition changes.
08	Essentially an editorial revision to clarify records processing and better reflect actual processing steps.
09	Revised to implement Process Validation and Re-engineering procedure changes.
10	Revised to clarify the interface with the YMP Requirements Matrix Coordinator and to set the SNL procedure matrix at the "procedure" level to interface with the QARD Requirements Matrix.
11	Editorial changes to reflect a change in title of the On-Site QA Representative from OQA Representative to QA Representative (see section 3.2) and to update procedure titles (see section 5.0).

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1.0 PURPOSE AND SCOPE

This procedure prescribes the process for the preparation, review, and approval of Quality Assurance Implementing Procedures (QAIPs), which are used as implementing documents for the Sandia National Laboratories (SNL) Civilian Radioactive Waste Management (CRWM) Quality Assurance Program. QAIPs are identified in QAIP 1-2 as part of the system of implementing documents for implementing the Department of Energy (DOE) Quality Assurance Requirements and Description (QARD) requirements.

Processing of other types of implementing documents used to control SNL CRWM activities are outside the scope of this procedure. These include Technical Procedures (TPs), which are processed under QAIP 20-1, and Project-level implementing documents adopted by the SNL CRWM QA Program. Project-level documents include selected Administrative Procedures (APs and YAPs). Preparation and issue of Project-level documents is done under the Office of Civilian Radioactive Waste Management (OCRWM) QA Program controls and is outside the scope of this procedure.

2.0 DEFINITIONS

Effective Date: The date on the procedure, instruction, or revision by which implementation is mandated.

Lab Lead: The manager designated as the project leader for CRWM work for SNL; previously designated the "Technical Project Officer."

Editorial Change: Grammar or spelling corrections, renumbering sections or attachments if the chronological sequence of work is not affected, changes to the title or number of the document, or updates to organizational titles if there is no change in responsibilities.

SNL Procedure Requirements Matrix: Identifies QARD requirements implemented by the specific SNL CRWM Quality Assurance Program procedures (i.e.QAIP).

3.0 PROCEDURE

3.1 Preparing a New or Revised Procedure

3.1.1 The **responsible author** prepares a new or revised procedure, which shall prescribe how an activity is to be performed, by completing the following steps.

1. Identify QARD requirements to be implemented by the procedure.
2. Define a series of sequential actions to implement the applicable requirements consistent with graded application of QA controls (QARD Section 2.2.4). Format and content guidance is provided in Appendix A. For revisions, consider any commitments identified in the revision history, and ensure that changes to commitments are appropriate and intentional.
3. Implementing documents shall include a revision history describing changes made and the reasons for the changes.

4. Implementing documents shall include the following information as appropriate to the nature, scope, and circumstances of the work being performed:
   a) Responsibilities and organizational interfaces of organizations affected by the document;
   b) Technical and regulatory requirements;
   c) A sequential description of the work to be performed, including controls for altering the sequence of required operations;
   d) Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished;
   e) Prerequisites, limits, precautions, process parameters, and environmental conditions;
   f) Quality verification points and hold points;
   g) Methods for determining that the work was performed as required;
   h) Identification of QA records generated by the document;
   i) Identification of associated items and activities; and
   j) the organization or individual responsible for submitting QA records to the records management system.
5. Prepare or update the SNL Procedure Requirements Matrix, as per AP-2.19Q, by preparing a list identifying the requirements of the QARD that the new or revised procedure addresses or obtain a 012 report from the RTN Web for an existing procedure and mark-up accordingly.

3.2 Reviewing, Approving, and Assigning an Effective Date

The **responsible author** initiates QA and management review and comment resolution per AP-2.14Q for all but editorial changes, supplying reviewers with a justification for the procedure or procedure revision, review criteria, review forms, revised SNL Procedure Requirements Matrix, and the draft procedure. The **QA Representative** performs the QA review and an **SNL Department Manager** performs the management review.

3.2.1 QA Review

For new or revised procedures, the **QA Reviewer** performs the QA review using the following review criteria:

1. Verify the inclusion of applicable quality requirements and controls.
2. Verify that referenced documents, including those generated outside of the SNL CRWM, are appropriate, current, and not in conflict with applicable requirements.

The **QA reviewer** also reviews the SNL Procedure Requirements Matrix to verify that it adequately and correctly identifies QARD requirements implemented by the new or revised procedure.

3.2.2 Management Review

The **management reviewer** reviews the procedure or revision using the following review criteria:

1. Adequacy of process detail;
2. Consistency with management policy and direction;
3. Clarity of implementation steps; and
4. Responsibilities and organizational interfaces are appropriately defined.

3.2.3 Approval and Effective Date

The **responsible author** signs and obtains **QA Reviewer** concurrence and **SNL Lab Lead** (or delegate) approval signatures on the cover page. These signatures indicate that the document was reviewed, review comments were satisfactorily resolved and incorporated, the associated SNL Procedure Requirements Matrix has been accepted by QA, and the document is approved for use on the effective date.

The **responsible author** enters an effective date (typically 5-10 working days to permit processing) and transmits to the **SNL document control staff** per AP-6.1Q: the approved procedure; a copy of the approved procedure in an acceptable word processor format; review documentation; approved SNL Procedure Requirements Matrix, and any other documentation required by AP-6.1Q.

3.3 Controlled Issue

Following receipt of the approved procedure, updated SNL Procedure Requirements Matrix, and review documentation, the **SNL document control staff**:

1. Issues the document as a controlled document per AP-6.1Q;
2. Forwards a copy of the SNL Procedure Requirements Matrix to the Requirements Matrix Coordinator in accordance with AP-2.19Q.
3. Submits records in accordance with AP-17.1Q.

3.4 Expedited Changes

The **SNL Lab Lead** may authorize an expedited change if an activity cannot be performed as described in a procedure and the normal change process would cause unreasonable delays. In this situation, the **SNL Lab Lead** documents the change, ensures that affected personnel are notified in a timely manner, and assigns a **responsible author** to process the change through the QAIP 5-1 process within 30 working days. The **responsible author** shall perform and document an evaluation of work performed during the interim period if the normal review process results in a change different than the expedited change. This documentation is submitted to document control staff upon approval and issue (Section 3.3.)

4.0 RECORDS

The following QA records generated as a result of implementing this procedure are submitted to project records in accordance with AP-17.1Q by the **document control staff** upon issuance as a controlled document under AP-6.1Q:

QA Records
Approved Procedure
Approved SNL Procedure Requirements Matrix
Expedited Change Impact Evaluation
AP-2.14Q Review Documentation*

5.0 REFERENCES

AP-2.14Q	Review of Technical Products and Data
AP-2.19Q	Quality Assurance Requirements and Description Requirements Matrix and Impact Evaluation
AP-6.1Q	Controlled Distribution
AP-17.1Q	Record Source Responsibilities for Inclusionary Records

6.0 APPENDIX

Appendix A. Procedure Format and Content (2 pages)

Appendix A. Procedure Format and Content Guidance

Cover Page:
Prepare a cover page similar to that of this procedure. The procedure identifier includes the acronym "QAIP" and a number based on a combination of the QAIP Series Number (the QARD Section from which requirements are primarily drawn) and a number designating the specific procedure, e.g. QAIP 5-1 is the first procedure in the "5" series.

Number new procedures as Rev.00 and revisions sequentially beginning with 01. Identify changes to revised procedure with vertical bars in the outside margin, adjacent to each change. If changes are extensive, the change bars may be omitted, if described in the Revision History.

Revision History:
Prepare a short narrative description of changes incorporated in all revisions of the procedure.

Table of Contents:
Develop a Table of Contents to aid in the use of a procedure for procedures with more than five pages or multiple appendices.

Body:
The procedure body should consist of the following in listed order:

1.0 Purpose and Scope: This section states what the procedure is intended to accomplish, describes the extent to which the procedure applies to specific organizations; identifies activities, tasks, or personnel affected by the procedure; and, if appropriate, describes the activities specifically excluded from the procedure's scope. Describe the relationship of this procedure to other procedures.

2.0 Definitions: Includes descriptions of terms that require specific definition to avoid misinterpretation. QARD Glossary definitions should be used unless there is justification for use of an SNL-unique definition.

3.0 Procedure: The procedure section provides a prescription for performing the procedure activity. Playscript format may be useful for processes that require multiple interactions between individuals. Alternatively, procedures may be written to identify responsible individuals and requirements. A process flow diagram may be useful to include to simplify use of the procedure. Checklists may also be useful to the procedure user in following the process.

Some general guidelines for preparing procedures include:

a. Identify individuals and organizations responsible for specific actions. This specifically includes identifying the individual responsible for submitting the QA records to the records management system.
b. Number the action steps.
c. Specify actions in the active, present tense voice and in a step-by-step logical sequence that will result in the completion of the desired activity. Each action step should be clear and concise, but sufficiently detailed to be unambiguous. Include references to other procedures in the step for which they apply.

Appendix A. Procedure Format and Content Guidance
(Concluded)

d. Use the action verbs, "may", "shall", and "should" as follows:
   (1) **May:** Denotes an action which is completed at the discretion of the person implementing the procedure or instruction.
   (2) **Shall:** Denotes an action required by a CRWM commitment, QA Program requirement, or related requirements document.
   (3) **Should:** Denotes a guideline action that is a preferred practice. These actions include good practices that are desirable for achieving uniformity or consistency of administration but do not arise from QA requirements. "Should" is implied when no auxiliary verb (shall or may) is used.

e. Note that unless specifically stated as such, the order of the specified actions presented in the QAIP does not imply that actions be carried out in a mandatory sequence.

4.0 Records:
Depending on the nature of the procedure, select the appropriate records description from the following:

1. If QA records are generated by the procedure, include the statement:
   "The following QA records generated as a result of implementing this procedure are prepared and submitted as project records in accordance with AP-17.1Q:"
   List the individual records and associated designator [QA:QA for QA records or QA:N/A for non-QA records] for each record type generated by the procedure. If data records are generated by the procedure, also reference AP-SIII.3Q in the above statement."

2. If QA records are generated by the procedure but processed by another procedure, use the statement:
   "The QA records generated as a result of implementing this procedure are prepared and submitted by the record source in the applicable procedure:

   "QA Records" "Procedure"

   Tabulate the records, record designations (QA:QA or QA:N/A) and the procedure under which each record is submitted.

3. If no records are generated by the procedure, indicate that explicitly.

5.0 References:
List all documents referenced in the procedure. Referenced documents should be applicable and current and should not conflict with applicable requirements.

6.0 Appendices:
List any appendices in the Table of Contents or at the end of the body of the procedure. A procedure that produces a document should summarize the format and content elements in an appendix unless the material is more appropriately located in the body of the procedure. Descriptive information used to provide background or explanation and that cannot be succinctly given in a note should be summarized in an appendix.